DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-21, as well as the species TB4 (claims 1-4, 6-14, 17-18, and 20-21) in the reply filed on 8/8/11 is acknowledged.

Claims 1-29 are pending.

Claims 5, 15-16, 19 and 22-29 are withdrawn as being drawn to non-elected inventions.

Claims 1-4, 6-14, 17-18 and 20-21 are under examination.

Information Disclosure Statement

The information disclosure statements filed 6/21/06, 9/18/09 and 8/13/10 are acknowledged. A signed copy of each is enclosed hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-14, 17-18 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treatment for treating, or reducing a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4, does not reasonably provide enablement for any preventing or inhibiting a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The invention is drawn to a method of treatment for treating, preventing, inhibiting or reducing a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4. The breadth of the claims is undue with regard to the prevention or inhibition of a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4.

The instant specification does not provide any guidance for the prevention or inhibition of a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4. The instant specification discloses treatment and reduction of poison ivy, but not prevention or inhibition. See, for example, page 8, example 1.

Without such guidance one of ordinary skill in the art would be burdened with undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-14, 17-18 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 recite "...or a conservative variant thereof..." This is vague and indefinite as to the metes and bounds of the envisioned conservative variant, in referring to SEQ ID NO:1.

The claims are indefinite because it is unclear if only conservative amino acids can be substituted for LKKTET or conservative variants include no-conservative amino acids in certain position so long as the activity of the peptide is retained. Thus, one cannot readily ascertain the structural modification necessary to render a LKKTET variant "conservative variant".

All other claims depend directly or indirectly from the rejected claim and are therefore, also rejected for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6-14, 17-18, and 20-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Goldstein et al (WO 03/020215).

The instant invention is drawn to a method of treatment for treating, preventing, inhibiting or reducing a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4.

Goldstein et al. discloses a method of treatment for promoting healing or preventing damage to tissue comprising administering thymosin beta 4. See, for example, claims 1-5, 9-10, 12 and 15. Golstein et al. discloses administration may include intravenous, intrparitoneal, intramuscular or subcutaneous injections, or inhalation, transdermal or oral administration of the composition containing thymosin beta 4. See, for example, page 3, lines 29-31. Goldstein et al. discloses other proteins useful in the method of treatment, such proteins are LKKTET, TB9, TB10, TB11, TB12, TB13, TB14, Tb15, gelsolin, DBP, profiling, cofilin, adservertin, propomyosin, fincilin, depactin, vilin, fragmin, severin, and acumentin. See, for example, page 4, lines 7-34.

Therefore, the cited reference is deemed to anticipate the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-14, 17-18 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleinman et al (WO 00/06190).

The instant invention is drawn to a method of treatment for treating, preventing, inhibiting or reducing a biological or immunological response to a reactive chemical agent, biological agent or toxin comprising administering thymosin beta 4.

Kleiman discloses a method of promoting tissue repair and wound healing. The method utilizies thymosin beta 4 (TB4) to promote tissue repair and wound healing by administration to the subject a wound-healing effective amount of a composition containing a wound healing polypeptide comprising the amino acid sequence LKKTET and conservative variants thereof having wound healing activity. See, for example, entire document and particularly, abstract, claims 1-2, 5-7, 13, 16-18, 23-24, 34-36, 38-39 and 41-44.

Therefore, the cited reference is deemed to anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-14, 17-18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al (WO 03/020215) in view of Kleinman et al (WO 00/06190)..

Goldstein beneficially discloses a method of treatment for promoting healing or preventing damage to tissue comprising administering thymosin beta 4. See entire document including, for example, Abstract.

Kleinman beneficially discloses a method of promoting tissue repair and wound healing. The method utilizies thymosin beta 4 (TB4) to promote tissue repair and wound healing by administration to the subject a wound-healing effective amount of a composition containing a wound healing polypeptide comprising the amino acid sequence LKKTET and conservative variants thereof having wound healing activity. See, for example, entire document and particularly, abstract, claims 1-2, 5-7, 13, 16-18, 23-24, 34-36, 38-39 and 41-44.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the peptide agent, based upon the overall beneficial teachings provided by Goldstein and Kleinman, as discussed above. If not expressly taught, the result-effective adjustment of conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0971. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT

/Cecilia J Tsang/

Supervisory Patent Examiner, Art Unit 1654